CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefore. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS/ARGUMENTS

Claims 1-27, 43, 45-50, 53-63, 65-70, 72-74, and 76-81 were pending. Claims 11-16, 19-20, 24, 43, 45, 47-50, 61-63, 65-68, 76-77, and 79-81 are withdrawn. By this Amendment, claims 1, 6, 17-18, 21, 25-27, 53, 55, 58, 69-70, 72-74, and 78 have been amended, new claims 82-87 have been added and claims 3-5, 7-10, 22-23, 46, 56-57, and 59-60 have been canceled without prejudice or disclaimer. No new matter has been added. Accordingly, claims 1-2, 6, 17, 18, 21, 25-27, 53-55, 58, 69-70, 72-74, and 78 are pending.

Claims Objections

In response to the claim objections, applicants have amended claims 53 and 78 and canceled claims 7 and 46 which no longer encompass non-elected embodiments. In addition, claim 10 has been canceled. The dependent claims have also been amended so that "A" has been replaced with "The." Claim 23 has been canceled. Claim 78 has been amended so that "BI" has been deleted.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw these objections.

Claim rejections under 35 U.S.C. §112, first paragraph, enablement

The Examiner rejected claims 1-10, 17-18, 21-23, 25, 27, 46, 53-60, 69-70, 72-74, and 78 as not being enabled.

In response, applicants have amended independent claim 1 which now reads as a method of treating or ameliorating chronic heart failure in a patient the method comprising administering to the patient an effective amount of a compound, wherein the compound is a bile acid, that is able to reduce the production, absorption and/or the effect of an endotoxin in human blood. As the Examiner will note, the claim no longer reads on preventing heart failure in a patient comprising administering to the patient any or all compounds. The other claims either directly or indirectly depend on claim 1.

Applicants note that Example 12 in the specification describes an in vivo experiment administering a bile acid to patients with cachexia due to liver cirrhosis showing decreased TNF-level in plasma. Example 1 also shows that chronic and acute heart failure is caused by increased TNF-level in plasma. Thus, one skilled in the art would conclude with these two Examples that administering bile acids to a patient suffering from acute or chronic heart failure with increased TNF-level will lead to decreasing TNF-level in plasma and ameliorating chronic or acute heart failure in the patient.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim rejections under 35 U.S.C. §112, first paragraph, written description

The Examiner rejected claims 1-10, 17-18, 21-23, 25, 27, 46, 53-60, 69-70, 72-74, and 78 under the written description requirement.

In response, as applicants have noted above, independent claim 1 has been amended to remove the term "all compounds" in place with "bile acid." The structures of bile acids are known by one skilled in the art. The remaining claims either directly or directly depend on claim 1.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 22 and 23 as being indefinite for lack of an antecedent basis. In response, applicants have canceled claims 22 and 23.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim rejections under 35 U.S.C. §102(b)

The Examiner rejected claims 1-2, 17-18, 25-26, 53-54. 69-70, 72-72, and 75 as being anticipated by Kambayashi et al. and Matsumori et al and rejected claims 53, 57-58, 72-73, and 78 as being anticipated by EP 0528312A1.

In response applicants have amended independent claim 1 which now specifically recite bile acids. Kambayashi and Matsumori disclose a method for treating congestive heart failure using the experimental drug vesnarinone, which inhibits the LPS stimulated release of TNF. However, Vesnarinone is 3,4-Dihydro-6(4-(3,4-dimethoxybenzozl)-1-piperazinyl)-2(1H)-quinolinone, which does not concern the group of bile acids. Vesnarinone shows a totally different chemical structure, from which one expects different functional properties. Thus, amended claim 1 is not anticipated by either reference because they do not teach bile acids. In order to show anticipation, the references must teach every element of the claimed invention, which they clearly fail to do so.

In response to the EP document, applicants assert that the reference simply discloses oral administration of bile acids and their salts in the treatment of billiary cirrhosis and chronic and cholestatic hepatopathies, but does not teach reducing elevated LPS levels in patients by administering bile acid either intravenously, rectally, or orally. Thus, the reference fails to teach every element of the claimed invention.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw these rejections.

Claim rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 3-4, 7-10, 21-23, 27, 46, 53, 55-56, 59-60, 74, and 78 as being obvious over Kambayashi or Matsumori in view of U.S. Patent No. 6,509,317.

In response, applicants assert that the references taken alone or together do not teach or suggest all the elements of the claimed invention. They do not teach or suggest bile acids to reduce elevated levels of LPS in patients.

CONCLUSION

Based on the foregoing remarks it is believed that the claims are in condition for allowance.

Respectfully Submitted,

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